**2362. Misbranding of Lanteen cup diaphragm and jelly set. U. S. v. 159 Dozen Packages * * *.** (F. D. C. No. 20251. Sample No. 29667–H.)

LIBEL FILED: June 20, 1946, Northern District of California; amended libel filed April 1, 1947.

ALLEGED SHIPMENT: On or about April 18 and 19, 1946, by Lanteen Medical Laboratories, Inc., from Chicago, Ill.

PRODUCT: 159 dozen articles of device at San Francisco, Calif., which were labeled in part "Lanteen Cup Diaphragm and Jelly Set." Each set consisted of a rubber diaphragm, two tubes of jelly, and a blooklet entitled "Directions For Marriage Hygiene."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the articles was false and misleading, since it represented and suggested that the rubber diaphragm and jelly were effective in preventing conception when used as directed, whereas they were not effective for such purpose.

DISPOSITION: April 23, 1948. Lanteen Medical Laboratories, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered. The decree made no finding on the charge under Section 502 (a), but found that the articles were misbranded in violation of Section 502 (f) (1), in that statements and designs in the booklet represented and suggested that the directions contained in the booklet were adequate and sufficient for the use of the product in preventing conception, whereas the directions for use were not adequate and sufficient for such purpose. The product was ordered released under bond to be relabeled.

## DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

**2363. Adulteration of Tebsin Tablets. U. S. v. S. O. Barnes & Son and Alfred O. Barnes. Motion to strike denied. Plea of nolo contendere. Fine of $1.000 against each defendant.** (F. D. C. No. 20983. Sample Nos. 31260–H, 58847–H.)

INDICTMENT RETURNED: March 12, 1947, Southern District of California, against S. O. Barnes & Son, a partnership, Gardena, Calif., and Alfred O. Barnes, a partner in the partnership, for the offense of giving a false guaranty.

ALLEGED VIOLATION: On or about January 25, 1945, the defendants caused to be given to W. B. Nisbet, trading as the W. B. Nisbet Co., of Los Angeles, California., a guaranty providing that no drug shipped or delivered by the defendants to the W. B. Nisbet Co., described in the guaranty as the "Distributor," would be misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act; that the potency of the vitamin content of all merchandise furnished to the distributor was guarantied for a period of 6 months from the date of shipment or delivery to the distributor; that labels used on all merchandise furnished to the distributor were to be furnished and placed on the merchandise by the distributor; that all labels used by the distributor must conform to all rules and regulations of the Food and Drug Administration; and that the distributor would assume full responsibility for any variation from the above in respect to information added to or omitted from labels used, as required by the Food and Drug Administration, and would accept full responsibility for any charges of adulteration or misbranding that may result therefrom.

On or about February 22, 1946, the defendant caused to be delivered to W. B. Nisbet at Los Angeles, Calif., a number of tablets, and between that date and March 28, 1946, W. B. Nisbet packed the tablets into bottles bearing the label "Tebsin Tablets" and delivered them to Tebsin Sales, Inc., at Los Angeles, Calif. Between March 19 and 28, 1946, Tebsin Sales, Inc., shipped the tablets from the State of California into the State of Washington. The Tablets so guarantied, delivered, and shipped were adulterated.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the tablets consisted in part of a filthy substance by reason of the presence of rodent hairs and rodent hair fragments; and, Section 501 (a) (2), they had been prepared, packed, and held under insanitary conditions whereby they may have become contaminated with filth.

The indictment alleged also that the defendant had given a false guaranty with respect to a food known as *Beir-Nes Tablets*, as reported in notices of judgment on foods.

DISPOSITION: The defendants moved to strike from the indictment the allegations with respect to the shipment of the product in interstate commerce,

on the grounds that the defendants could not be criminally liable for the acts of third parties or for an act in which the defendants did not participate. The defendants' motion was denied by the court on April 21, 1947. Thereafter, a plea of nolo contendere was entered on behalf of the defendants, and on September 15, 1947, the court imposed a fine of $1,000 against each defendant.

## DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

**2364. Adulteration and misbranding of Met-Estrin. U. S. v. Metropolitan Laboratories, Inc., and Rudolph N. Price. Pleas of guilty. Fine, $500 against defendants jointly.** (F. D. C. No. 17856. Sample Nos. 6027–H, 6028–H, 16540–H.)

INFORMATION FILED: January 21, 1948, Southern District of New York, against the Metropolitan Laboratories, Inc., New York, N. Y., and Rudolph N. Price, president of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of January 23 and April 10, 1945, from the State of New York into the States of New Jersey and Illinois.

LABEL, IN PART: "Metro Met-Estrin (Estrogenic Substance)."

NATURE OF CHARGE: Adulteration, Section 501 (d), an oil solution of estradiol with insignificant amounts of estrone or other ketosteroids had been substituted in whole or in part for a mixture of natural estrogens derived from pregnancy urine, which the article purported and was represented to be.

Misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, since the label designation "Estrogenic Substance" is not the specific name of any particular substance but is a generic name for a class of substances.

DISPOSITION: April 6, 1948. Pleas of guilty having been entered, the court imposed a fine of $500 against the defendants jointly.

**2365. Adulteration and misbranding of Thionicavin No. 2. U. S. v. Chicago Pharmacal Co. and Chester H. Taylor and William B. Taylor, Jr. Pleas of guilty. Fine, $1,000.** (F. D. C. No. 23217. Sample Nos. 57491–H, 64989–H.)

INFORMATION FILED: September 9, 1947, Northern District of Illinois, against the Chicago Pharmacal Co., a corporation, Chicago, Ill., and Chester H. Taylor, president, and William B. Taylor, Jr., secretary and treasurer, of the corporation.

ALLEGED SHIPMENT: On or about September 9 and 10, 1946, from the State of Illinois into the States of Vermont and New York.

LABEL, IN PART: "Sterile Solution No. 54B Thionicavin No. 2 For Intramuscular or Intravenous Use Multiple Dose Package."

NATURE OF CHARGE: Adulteration, Section 501 (d), a product containing estradiol in sesame oil had been substituted for a product containing thiamine hydrochloride, riboflavin, pyridoxine hydrochloride, nicotinamide, urea, and redistilled water, which the article purported and was represented to be.

Misbranding, Section 502 (a), the labels of the article represented and suggested that the article was suitable for intravenous use; that each cubic centimeter of the article contained 100 milligrams of thiamine hydrochloride, 5 milligrams of riboflavin, 2.5 milligrams of pyridoxine hydrochloride, 100 milligrams of nicotinamide, 100 milligrams of urea, 10 milligrams of benzyl alcohol, and redistilled water sufficient to make one cubic centimeter; that the article was suitable for use in correcting and preventing beriberi, pellagra, and anorexia, in securing optimal growth of infants and children, in impaired lactation, in pernicious vomiting of pregnancy, and in deficiencies of the B vitamins; and that one cubic centimeter of the article contained about fifty times the thiamine, two times the riboflavin, and five and one-half times the nicotinamide daily optimum adult intake. The article consisted of estradiol in sesame oil and was not suitable for intravenous use; it did not contain thiamine hydrochloride, riboflavin, pyridoxine hydrochloride, nicotinamide, urea, and redistilled water; it was not suitable for use for the purposes represented; and it would not furnish any thiamine, riboflavin, and nicotinamide.

DISPOSITION: October 7, 1947. Pleas of guilty having been entered on behalf of all defendants, the court imposed a fine of $1,000 and costs and ordered that the fine be paid by the corporation.